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July 7, 1999

Susan M. Pilch, Ph.D.
Nutrition Health Claims and Dietary Supplements
CFSAN, Office of Special Nutritionals
Food and Drug Administration
200 C Street, SW
Washington, DC 20204

Re: Health Claim Petition for Folic Acid, Vitamin B6, and Vitamin B12 Dietary
Supplements and Vascular Disease

Dear Dr. Pilch,

On behalf of Julian M. Whitaker, MD, American Preventive Medical Association, Durk Pearson and Sandy Shaw, and Pure Encapsulations, Inc. (collectively "Petitioners") we hereby submit this supplemental response to the agency's letter of June 7, 1999. In compliance with the agency's request, the Petitioners submit the following information

Analytical Methods:

In addition to the analysis methods described in the US Pharmacopoeia (Attachment 3), the amount of vitamin B6, vitamin B12, and folic acid can be determined by Association of Official Analytical Chemists International (AOAC) official testing methods. The amount of vitamin B6 contained in a dietary supplement combination product can be determined by AOAC official method numbers 961.15 and 960.46. The amount of vitamin B12 contained in a dietary supplement combination product can be determined by AOAC official method numbers 952.20 and 960.46. The amount of folic acid contained in a combination dietary supplement can be determined by AOAC official method numbers 944.12 and 960.46. Those official AOAC methods are described in the *Official Methods of Analysis of AOAC International*, 16th Ed. (Gaithersburg, MD: AOAC International), 1997, Chapter 45.

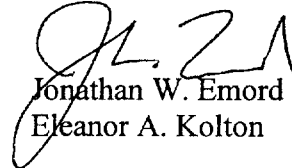
99P-3029

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Dr. Susan Pilch
July 7, 1999
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We are filing an original and one copy of this letter. Feel free to call if you have any questions.

Sincerely,



Jonathan W. Emord
Eleanor A. Kolton